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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,484	01/28/2000	Adriaan Anthonius Wilhelmus Marie Van Loon	1999.454 US	2307

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INTERVET INC
405 STATE STREET
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MILLSBORO, DE 19966

EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/493,484

Applicant(s)

VAN LOON, ADRIAAN
ANTHONIUS WILHELMUS M

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 10-13 and 15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are allowed.
- 6) ☒ Claim(s) 5-9 and 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the response filed 13 February, 2003. No amendments to the claim language accompanied the response. Claims 5-9, 14, and 16-25 are currently under examination while claims 1-4, 10-13, and 15 stand withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

35 U.S.C. § 112, First Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 5-9 and 16-25 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims are directed toward vaccine compositions comprising a large genus of avian reoviruses that are capable of inducing antiserum that displays different degrees of inhibition (e.g., 75%, 80%, or 90%) as determined by a plaque reduction assay. Other identifying criteria include negative limitations specifying that the avian reoviruses of interest do not react with a series of monoclonal antibodies.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of avian reoviruses that are present in the vaccine composition. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every

species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and

the method of making the claimed invention.

The disclosure fails to provide adequate guidance pertaining to a number of these factors as follows:

1) The disclosure fails to provide the complete nucleotide or amino acid sequence of any given avian reovirus. While it is noted that the disclosure describes the isolation and preliminary characterization of a single avian reovirus (designated ERS) bearing the E.C.A.C.C. accession no. 9901475, this is the only virus that was isolated in the specification. Nucleotide and amino

acid sequence data was not provided for this isolate or any other isolate. Thus, the disclosure fails to identify the structure, and any critical molecular determinants, that modulate the phenotypic properties of any given avian reovirus.

2) The phenotypic properties used to describe the claimed invention fail to provide any further illumination pertaining to the genotypic properties of any given isolate. Limitations are directed toward the ability of any given virus to induce antiserum in an animal that produces a certain degree of plaque reduction when measured in an art-recognized plaque reduction assay. Another defining property is directed toward a negative limitation that simply specifies that the avian reovirus of interest does not react with a small group of monoclonal antibodies of undefined specificity. However, these simple defining criteria fail to provide any guidance pertaining to the genotype of any given isolate. Thus, the skilled artisan has been asked to guess as to which isolate might meet the claimed limitations.

3) The disclosure fails to provide any clear correlation between the genotype and phenotype of any given reovirus. For instance, the claimed genus is being defined by their ability to induce antisera with a certain neutralizing activity. However, the disclosure fails to provide any correlation between the induction of said antisera and corresponding genotypic/phenotypic changes in

the reoviral genome. The disclosure fails to identify any critical antigenic or immunogenic determinants. Nothing in the disclosure would lead the skilled artisan to any particular isolate other than the one bearing the ECACC designation 9901475. Thus, the skilled
5 artisan cannot readily ascertain if they are in possession of the claimed invention.

4) The disclosure fails to provide a reproducible method for making a homogenous population of avian reoviruses with similar structures and functions. The avian reovirus of interest was isolated from
10 chickens having digestive problems and passaged on a suitable cell lines. The ability of this virus to induce neutralizing antisera was assessed using a plaque reduction assay. However, this assay fails to provide any guidance pertaining to the molecular determinants that modulate the desired phenotype of the virus. It
15 has been well-documented that the avian reoviruses display considerable genotypic/phenotypic heterogeneity (Nersessian et al., 1989; Rosenberger et al., 1989; Patrick et al., 2001; Jones, 2002; Kapczynski et al., 2002). Thus, using the described methodology, the skilled artisan can only guess as to what the final product
20 will be.

When all the aforementioned factors are considered in toto, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention. The skilled artisan would only conclude that applicants were in possession of a single avian
25 reovirus having the E.C.A.C.C. accession no. 9901475. Appropriately drafted claim language directed toward this embodiment would be acceptable.

Response to Arguments

30 4. Applicant provides a number of arguments as follows: 1) The art recognizes the characterization of viruses by their antigenicity. 2) The disclosure provides numerous examples of isolated avian

reoviruses with the defined characteristics. 3) Applicant contends that the case law relied upon fails to support a *prima facie* case for lack of written description.

Concerning the first point, the Examiner does not dispute the finding that serological properties of are often used in the classification of viruses. However, merely citing a particular immunological property without a further understanding of the molecular determinants modulating that activity fails to provide any further illumination pertaining to the genotype of any given isolate. Applicants are attempting to define a large genus of genotypically/phenotypically independent and distinct viruses based upon a rather generic assay. The assay relied upon fails to provide the skilled artisan with any guidance pertaining to the genotypic modifications that impart those properties to any given isolate. This is why those skilled in the art rely upon several properties, in addition to serology, to identify and classify any given virus or isolate. Additional properties routinely employed include virion morphology (e.g., virion size, virion shape, presence of absence of an envelope, capsid symmetry and structure), physicochemical properties (e.g., virion molecular mass, virion buoyant density, pH stability, cation stability, solvent stability, detergent stability), genomic characteristics (e.g., type of nucleic acid, genome size, strandedness, linearity, segmentation, nucleotide sequence, G/C content, presence of 5' terminal cap, presence of 5' terminal covalently linked protein), proteins (e.g., number, size, structural functions, nonstructural functions, amino acid sequence, posttranslational modifications), lipid content, carbohydrate content, genome organization and replication strategies, antigenic properties, and biologic properties (e.g., host range, mode of transmission, vector relationships, tissue tropism). The claim language fails to incorporate any meaningful structural or functional limitations that would readily allow the skilled artisan to identify whether or not they were in possession

of the claimed subject matter..

Concerning the second point, while it appears that more than one ERS isolate was identified (e.g., see Table 3, p. 19), nevertheless, only one specific isolate was deposited (ECACC No. 99011475). The disclosure fails to provide any detailed structural or functional characterizations of these other isolates. The disclosure fails to provide a single replication-competent molecular clone. The disclosure fails to provide detailed nucleotide sequence analyses from any of the isolates, including the deposited isolate. Thus, the skilled artisan cannot even begin to ascertain the coding potential of any given isolate. The skilled artisan cannot even begin to ascertain which genomic segments, and the modifications contained therein, that are responsible for the desired phenotype of the virus. Thus, the skilled artisan would reasonably conclude that applicants were in possession of a single avian reovirus, which has the ECACC designation no. 99011475. If additional ERS isolates have been deposited with an appropriate agency, the Examiner would consider appropriate drafted claim language directed toward these embodiments (i.e., A vaccine comprising an avian reovirus ... which is deposited at the ECACC under accession no. XXXXXXXX).

Concerning the third point, the case law relied upon in the rejection is directly relevant. As previously set forth, an applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of

such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. The aforementioned citations are not strictly limited to nucleic acids, but provide generally applicable principles to be used in assessing whether any given inventions meets the legal criteria set forth under this statute. The claimed invention is directed toward a large genus of poorly defined avian reoviruses. Contrary to applicant's assertion, the claims are not directed toward a "living" organism but are directed to a virus. Viruses are not capable of replication in the absence of a host. However, the *sine qua non* of any given virus is its genome and the proteins encoded thereby. So in essence, the claims are really directed toward an aggregation of "biomolecules" whose various properties contribute to the final

phenotype. The phenotypic properties of any given virus are influenced by these various proteins. The reoviruses contain 10 dsRNA genome segments within a non-enveloped, icosahedral double capsid. These segments can be further divided into large (L1, 2, 3), medium (M1, 2, 3), and small (S1, 2, 3, 4). The disclosure fails to provide any guidance pertaining to changes within any of these segments that correlate with the claimed phenotypic properties of the generic class of avian reoviruses. Applicant has no knowledge or understanding of which segments are critical for the desired phenotype. Thus, the applicant has clearly failed to meet the burden required under this statute. The law requires the invention to be clearly defined. Applicant has failed to provide sufficient defining criteria.

Finality of Office Action

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

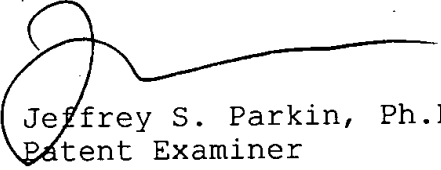
Correspondence

6. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be

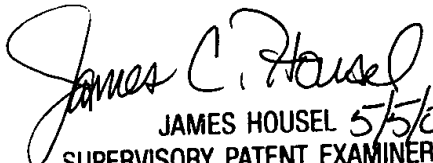
5 directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

10 7. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any
15 inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

03 May, 2003


JAMES HOUSEL 5/5/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600